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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,064	07/08/2003	Scott Happe	25436/2282	4769

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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,064	Applicant(s) HAPPE ET AL.	
	Examiner Robert B. Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 14-16 drawn to a recombinant polynucleotide comprising a first nucleic acid sequence a humanized *Renilla reniformis* green fluorescent protein (hrGFP) and a second heterologous nucleic acid sequence inserted internally into said first nucleic acid sequence encoding humanized hrGFP, said recombinant polynucleotide encoding a scaffold GFP, a recombinant vector containing the said polynucleotide and a cell containing the said vector, classified in class 536, subclass 23.1.
- II. Claims 11-13, drawn to a recombinant polypeptide comprising *Renilla reniformis* green fluorescent protein (hrGFP) and a heterologous peptide that is fused internally to said GFP, classified in class 530, subclass 350.
- III. Claims 17-18, drawn to a library of recombinant vectors comprising a plurality of recombinant polynucleotides wherein said recombinant polynucleotides comprise a first nucleic acid sequence encoding humanized *Renilla reniformis* green fluorescent protein (hrGFP) and second heterologous nucleic acid sequence inserted internally into said first nucleic acid sequence encoding hrGFP, wherein the members of the library comprise a plurality of different said second heterologous nucleic acid sequences, classified in class 436, subclass 536.

- IV. Claim 19, drawn to a method for identify a peptide conferring a phenotype of interest comprising the steps of: a) providing a plurality of cells, each cell containing a recombinant vector comprising a recombinant polynucleotide that encodes a recombinant polypeptide comprising *Renilla reniformis* Green fluorescent protein (hrGFP) and a heterologous random peptide wherein said heterologous random peptide is fused internally into said (hrGFP), under conditions wherein said recombinant polypeptide is expressed, and b) assaying said cells for said phenotype, classified in class 435, subclass 6.
- V. Claim 20, drawn to a method for identifying a peptide that interacts with a protein of interest the method comprising the steps of : a) introducing a library of recombinant vectors comprising recombinant polynucleotides that encode recombinant polypeptides into a plurality of host cells and maintaining said cells under conditions wherein said recombinant polypeptides are expressed, wherein said recombinant polypeptides comprise *Renilla reniformis* green fluorescent protein (hrGFP) fused to a transactivation domain and a heterologous randomized peptide fused internally into said hrGFP and, wherein said host cells contain a gene that encodes a protein of interest fused to a DNA binding domain, and a reporter gene functionally linked to a DNA sequence that binds said DNA binding domain, wherein expression of said reporter gene is regulated by said transactivation domain and; b) detecting expression of

said reporter gene, wherein detection of reporter gene expression identifies said heterologous random peptide as a peptide that interacts with the protein of interest, classified in class 436, subclass 543.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I and III, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects. The invention of group I is a recombinant polynucleotide comprising a first nucleic acid sequence a humanized *Renilla reniformis* green fluorescent protein (hrGFP) and a second heterologous nucleic acid sequence inserted internally into said first nucleic acid sequence encoding humanized hrGFP, said recombinant polynucleotide encoding a scaffold GFP, a recombinant vector containing the said

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polynucleotide and a cell containing the said vector, the invention of Group II is a recombinant polypeptide comprising *Renilla reniformis* green fluorescent protein (hrGFP) and a heterologous peptide that is fused internally to said GFP, whereas the invention of Group III is a library of recombinant vectors comprising a plurality of recombinant polynucleotides wherein said recombinant polynucleotides comprise a first nucleic acid sequence encoding humanized *Renilla reniformis* green fluorescent protein (hrGFP) and second heterologous nucleic acid sequence inserted internally into said first nucleic acid sequence encoding hrGFP, wherein the members of the library comprise a plurality of different said second heterologous nucleic acid sequences.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects. The invention of Group IV is a method for identify a peptide conferring a phenotype of interest comprising the steps of: a) providing a plurality of cells, each cell containing a recombinant vector comprising a recombinant polynucleotide that encodes a recombinant polypeptide comprising *Renilla reniformis* Green fluorescent protein (hrGFP) and a heterologous random peptide wherein said heterologous random peptide is fused internally into said (hrGFP), under conditions wherein said recombinant polypeptide is expressed, and b) assaying said cells for said phenotype whereas the invention of Group V a method for identifying a peptide that interacts with a protein of interest the method comprising the steps of : a) introducing a library of recombinant

vectors comprising recombinant polynucleotides that encode recombinant polypeptides into a plurality of host cells and maintaining said cells under conditions wherein said recombinant polypeptides are expressed, wherein said recombinant polypeptides comprise *Renilla reniformis* green fluorescent protein (hrGFP) fused to a transactivation domain and a heterologous randomized peptide fused internally into said hrGFP and, wherein said host cells contain a gene that encodes a protein of interest fused to a DNA binding domain, and a reporter gene functionally linked to a DNA sequence that binds said DNA binding domain, wherein expression of said reporter gene is regulated by said transactivation domain and; b) detecting expression of said reporter gene, wherein detection of reporter gene expression identifies said heterologous random peptide as a peptide that interacts with the protein of interest.

The products of inventions of Groups I-III are not used in the method of the inventions of Groups IV-V (inventions are drawn to methods of identification not methods of using) and thus are patentably different.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi

Robert B. Mondesi
3-02-06